High Courts in the country. All such matters have been clubbed together and is at present pending adjudication before the Hon'ble Supreme Court of India for final decision.

Procedure adopted for permission of new drugs

*389. SHRI MUNAVVAR HASAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the procedure being adopted for the permission of new drugs;

(b) the normal time taken for the grant of permission for the new drugs;

(c) the names of the new drugs for which permission has been granted during this year; and

(d) the time taken in each case?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. C. P. THAKUR): (a) to (d) The requirement for evaluation of a new drug application for market authorisation are prescribed under rules 122A to E and Schedule 'Y' of the Drugs and Cosmetics Rules, 1945. The modalities *inter-alia* include initial evaluation of chemical and physical characterstics, animal toxicity, pharmacokinetics and pharmacodynamics of the drug. This evaluation is done by the office of the DCG(I) with the help of experts. It also involves approval of protocols for clinical trials as well as scrutiny of data generated by various clinical trials and result of the testing of the new drug by the Central Government Laboratories.

This evaluation of a new drug application is a complex process. The time taken varies according to the nature of the molecule/drug and depending upon the nature of the application. It may normally take more than five years for approval of Investigational New Drug (a drug molecule not tested on human beings anywhere in the world), about 1-3 years for the first time approval in India of a drug already approved elsewhere and about 2-3 months for subsequent applications by other manufacturers for drugs already approved for market authorisation in India. This is, however, subject to timely submission of all required data as per provision of Schedule 'Y' of the Drugs and Cosmetics Rules by the applicant. Certain categories of the drugs, *viz.* anti-cancer, anti-AIDS, etc. are examined on a fast track mode.

A list of New Drugs approved this year (1st Jan. 2001 to 30th June 2001) is annexed as statement.

Statement

New drugs approved by Drug Controller General (India) during the Period January 2001 to 30th June 2001

S.No.	Name of the Drug	Category	Date of receipt of application	Date of approval
1.	Sildenafil Citrate	Men Erectile dysfunction	2/6/1998	8/1/2001
2.**	Triflusalcaps 30 mg	Prevention of Thromboembolism	25/6/1996	17/1/2001
3.**	Thymosin Alfa 1 Inj.	Anti Hepa-B	28/10/1994	17/1/2001
4.*	Vinorelbin Tartrate Inj	Anti Cancer	6/2/2000	17/1/2001
5.	Clopidogrel	Anti Flatlet Aggregation Inhibitor	5/7/2000	2/2/2001
6.*	Indinavir Sulphate	Anti Aids	22/5/2000	1/2/2001
7.	Butenafine HCL cream 1%	Anti fungal	11/8/2000	14/2/2001
8.	Mitrazapine	Anti depression	10/4/2000	14/2/2001
9.	Doneprazal HCL	For Alzheirmer's D.	3/12/1998	20/3/2001
10.	Mosapride	Prokenetic agent	29/3/2000	13/3/2001
11.	Bupropion SR Tab. 150 mg.	Smoking cessation	12/7/2000	10/4/2001
12.	Reloxifen	Menopausal osteoporosis	13/10/1999	4/5/2001
13.*	Efavirenz 50/100/200 mg.	Anti HIV	27/4/2000	6/6/2001
14.	Moxifloxacin	Anti bacterial	March 1997	26/6/2001
15.	Misoprostol	Anti ulcer	3/4/1997	21/6/2001
16.*	Nelfinavir	Anti HIV	22/12/2000	29/6/2001

* Anti cancer / anti AIDS or immunosuppressive drugs

** Drugs referred to ICMR and Experts/

Hold on placement of Wagon orders to certain PSUs.

*390. SHRI DIPANKAR MUKHERJEE:
SHRIMATI CHANDRA KALA PANDEY:

Will the Minister of HEAVY INDUSTRIES AND PUBLIC ENTERPRISES be pleased to state:

(a) whether vigilance checks by Railways show that M/s. Burn Standard, Howrah and M/s. Burn Standard, Burnpur had used cheaper mild steel in place of certain steel supplied by Railways;

(b) if so, whether for the above reasons Railways have put a hold on